SUMMARY OF THE QUALITY SYSTEMS COMMITTEE MEETING APRIL 6, 1999

The Quality Systems (QS) Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on April 6, 1999, at 1 p.m. Eastern Daylight Time (EDT). The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency's (EPA) Region III. A list of action items is given in Attachment A. A list of participants is given in Attachment B. A list of parking lot issues is given in Attachment C. Attachment D presents the QS Committee approach to handling comments, comment acknowledgment form letter, commenter template, and guiding principles for reviewing comments and the standard. Attachment E presents the QS Committee responses to comments discussed during this teleconference. Changes to the language in Chapter 5 proposed at this teleconference are reflected in version 5.10.5 of the standard. *The purpose of the meeting was to: review action items from previous meetings, discuss comments received at the NELAC IVi meeting, discuss the revisions to the air testing requirements and discuss additional comments.*

REVIEW OF ACTION ITEMS FROM THE PREVIOUS TELECONFERENCE

The committee reviewed the action items from the previous meeting, which was held by teleconference on March 30th. Items not already completed or addressed at today's meeting will be carried over to the next meeting.

The version of Chapter 5 for publishing and distribution at NELAC V is due on April 29th.

DISCUSSION OF ISSUES RAISED AT NELAC IVI

The committee discussed several definitions in Appendix B of Chapter 5. Changes to existing definitions and new definitions are presented version 5.10.5 of Chapter 5. The following terms were discussed:

- Batch
- Media (New Definition)
- Sampling Media (New Definition)
- Method Blank
- Refrigeration
- Quantitation Limit
- Move Validation ahead of Verification
- Verification

SECTION D.5, AIR TESTING

The language in the opening paragraph was modified to make it clear that for air testing, the requirements of Chapter 5 (Sections 5.0 to 5.16 and Appendix B and C) still apply, except as specified in Section D.5.

The question was raised as to whether the references to the *Code of Federal Regulations Parts 50, 53, and 58* in Section D.5.6 should be included even though they were not directly used in developing the standards. The committee decided not to include them in the reference listing.

Section D.5.5, Training will be incorporated into the main body of the standard in Section 5.6.1. This will help make the format of Section D.5 consistent with the other sections in Appendix D.

INITIAL DEMONSTRATION OF CAPABILITY (IDOC)

The committee reviewed Mr. Donivan Porterfield's suggested changes (from December 13, 1998) to Section C.1 regarding a procedure for demonstrating IDOC. Mr. Porterfield will distribute a comparison of the current requirements to his proposed changes because many of the QS Committee participants did not have a copy of the proposed language. This comparison will be discussed at the next meeting.

A specific item for further review is Section C.1.b, which requires that a concentrate be diluted in a volume of clean matrix sufficient to prepare four aliquots at the required method volume to a concentration approximately 10 times the method-stated or laboratory-calculated method detection limit. Mr. Porterfield's proposed language has a more general requirement that would allow a laboratory more flexibility.

WHOLE EFFLUENT TOXICITY

A question was raised as to the origins of the current requirements for Whole Effluent Toxicity (WET) in Section D.2. It was pointed out that a subcommittee had been formed to develop this section, with participants who either regulated or conducted testing for WET. When drafting section D.2, the subcommittee tried to include important quality control (QC) requirements typically not included in WET methods.

COMMENTS RECEIVED

The committee reviewed the draft responses to comments received from Mr. Jack Hall of Quanterra. The initial draft responses were prepared by individual committee participants and reviewed by the committee at this meeting to develop a consensus response. The summary below is grouped by the section to which the comment refers and the committee participant that drafted the initial response. The detailed, consensus responses are presented in Attachment E.

Sections 5.11.3.c and 5.13.a.17: No changes were made to either of these sections. The language in Section 5.11.3.c was taken from ISO Guide 25 and the committee's understanding is that the term *preparation* includes preservation. The changes suggested in Section 5.12.a.17 were made in a subsequent version of Chapter 5 and should be reflected in the current version.

Sections C, 5.10.2.1, D.1.1.a.1.i, and ii: The term *and* between D1.1.a.1.i and D.1.1.a.1.ii was changed to *or*. Note that the attached responses from Mr. Mendenhall include an item not

discussed at this teleconference. The change proposed under the heading *QS Response NOTE 2:* is not a consensus response.

Sections D.1.1.b.1 Note, 5.9.3, 5.9.4.2.1.f, and 5.9.4.2.1.h: The note in Section D.1.1.b.1 was kept because it gives the laboratory some extra flexibility to substitute a matrix spike for an LCS. An editorial change was made to 5.9.4.2.1.f.

One of the comments received from Severn Trent Laboratories also addressed Section 5.9.4.2.1.f. The editorial change made above to Section 5.9.4.2.1.f addresses this comment. The consensus response to the comment on this specific section is presented in Attachment E. The remaining comments from Severn Trent Laboratories will be addressed at a later time.

NEXT MEETING

The next meeting is scheduled for April 20, 1999.

Attachment A

ACTION ITEMS
QUALITY SYSTEMS COMMITTEE
APRIL 6, 1999

Item No.	Action Item	Date to be Completed
1.	Mr. Raymond Frederici will provide an example form to address the requirements of the IDOC Certification Statement	
2.	Mr. Slayton to contact members of the QS Whole Effluent Toxicity (WET) subcommittee to see whether they will agree to addressing comments directed to the WET section (D.2) of Chapter 5.	
3.	Mr. Porterfield to distribute a side-by-side comparison of the current requirements in Section C.1 on Procedure for IDOC to the proposed changes for this section. QS Committee to review these changes.	April 20th teleconference
4.	Review Mr. Frederici's responses to comments from Quanterra on Sections 5.4.2, 5.7.1, and 5.11.3.	April 20th teleconference
5.	Review Mr. Mendenhall's proposed deletion of the first sentence in the second paragraph of Section D1.1.a.1.	April 20th teleconference
6.	Mr. Slayton to distribute an electronic copy of the combined glossary to QS Committee. Review glossary at the next teleconference.	
7.	The next teleconference is April 20th from 10 a.m. to 12 noon EST. The following meeting is April 28th from 2 to 5 p.m.	

Attachment B

PARTICIPANTS
QUALITY SYSTEMS COMMITTEE
APRIL 6, 1999

Name	Affiliation	Phone/Fax/E-mail
Slayton, Joseph Chair	U.S. EPA/Region 3	T: 410-305-2653 F: 410-305-2698 E: slayton.joe@epamail.epa.gov
Bruch, Mary	Mary Bruch Micro Reg. Inc.	T: 703-589-1514 F: 703-779-0267 E: --- none ---
Frederici, Raymond (Absent)	Recra Labnet	T: 708-534-5200 F: 708-534-5211 E: frederir@recra.com
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Nielsen, Jeffrey	City of Tallahassee, Water Quality Division	T: 850-891-1232 F: 850-891-1062 E: nielsenj@mail.ci.tlh.fl.us
Porterfield, Donivan	Los Alamos National Lab., AQ & CIM	T: 505-667-4710 F: 505-667-2601 E: dporterfield@lanl.gov
Siders, Scott (Absent)	Illinois EPA	T: 217-785-5163 F: 217-524-0944 E: epa6113@epa.state.il.us
Siegelman, Fred	USEPA/ORD/QAD	T: 202-564-5173 F: 202-564-2441 E: siegelman.frederic@epamail.epa.gov
Cross, Mike (Contractor Support)	Research Triangle Inst.	T: 202-728-2045 F: 202-728-2095 E: myc@rti.org

Attachment C

PARKING LOT ITEMS/ISSUES
QUALITY SYSTEMS COMMITTEE
APRIL 6, 1999

Items/issues will remain in the Parking Lot until they are completed.

1. Air Appendix

Need to review and finalize

2. Initial Demonstration of Capability (IDOC):

Need to address an IDOC for tests for which you can not spike. Also, does IDOC need to be universal and address all medias? Donivan Porterfield is lead.

3. Definitions/Glossary

Changes necessary to be consistent with Program Policy and Structure proposal. QS Committee will review definitions/glossary at interim meeting.

4. Need to vote in two new members to QS committee.

All candidates must be identified and voted upon by NELAC Committees by May 10, 1999. All appointments by the NELAC Chair must be complete by May 17, 1999.

5. Final QS Chapter for NELAC V

Final changes to standards are due to Research Triangle Institute by April 29, 1999 for posting on the NELAC Web page prior to the annual meeting. This version will be posted within a week and half of receipt and will remain as the final proposed text for Annual Meeting.

6. Agenda for NELAC V

Final committee agendas, including discussion items and times, are due to Elizabeth Dutrow by May 10, 1999.

Attachment D

ACKNOWLEDGEMENT LETTER, REVIEW GUIDELINES, AND COMMENTER TEMPLATE
QUALITY SYSTEMS COMMITTEE
APRIL 6, 1999

Date:

Dear :

On behalf of the Quality Systems Committee, thank you for your comments on the Chapter 5 standards of the National Environmental Laboratory Accreditation Conference (NELAC). The standards are routinely reviewed and updated. Continual improvement of the standards is the focal point of NELAC process. We encourage your continued written input as well as your attendance at the NELAC interim meeting and yearly conference. Also, our committee routinely schedules 1-2 open forum meetings during each calender year.

Our committee requests that all comments be supplied in electronic format (WordPerfect if possible) and that handwritten, hardcopy and the use of color fonts be avoided. Comments are considered by the QS committee on a first-come/first-serve basis. We have placed a template (table) for comments on the NELAC Web page, which we hope will ensure that the processes is efficient. With this process we hope that emphasis can be placed on consideration of the comments so that the available time is not spent in the mechanics of exchanging information (US Mail and re-typing comments). Routinely, each set of comments is assigned a QS leader who will complete the comment table including suggested language for any proposed changes to the NELAC standards. The Leader will guide a discussion of the comments during routine committee meetings. The minutes of the meeting (posted on the web site) will capture the information in the completed table from committee discussions, thoughts/rationale and present the final decisions.

Again, thank you for taking the time and effort to improve the NELAC Quality System standards.

Sincerely,
Joseph Slayton, Chair
Quality Systems Committee

QS Approach: Comments Received and QS Response:

1. A form letter will be sent to each commentor notifying them of receipt of the comment and of the QS's approach to reviewing comments and associated updates to the standards.

2. QS will consider the comments in the order received.

3. A QS committee member will be designated as the lead on each set (or up-set) of the comments from each commentor, who will provide written comments and who will lead a discussion with the full committee on any proposed changes to the standards (including providing the proposed standard language).

4. Proposed changes to the standards will be captured in the QS meeting minutes which are posted on the NELAC Web page.

5. All comments and written responses will be attached to QS meeting minutes.

6. No colors to be used in the comments nor in the response. Use double underlines for additions and strike-outs for removal of items.

7. All comments are to be provided in WordPerfect or rich text format using the following the following table:

GUIDING PRINCIPLES/REVIEW CRITERIA

The QS Committee established a set of criteria by which to evaluate the requirements specified in Chapter 5. The standards in Chapter 5 should meet the criteria listed below:

Flexible:

Allow laboratories freedom to use their experience and expertise in performing their work and allow for new and novel analytical methods and approaches, (e.g., Performance Based Measurement System [PBMS]). That the standards specify the "What" and avoid were possible the "How To", (e.g., control limits must be developed to determine if a QC check result is acceptable, the standards do not specify how the laboratory is to determine these limits).

Auditable:

Sufficient detail is included so that the accrediting authorities evaluate laboratories consistently and uniformly.

Practical/Essential:

The standards are necessary QA policies and QC procedures and that these standards should not place an unreasonable burden upon laboratories.

Widely Applicable:

International scope- consistent with ISO Guide 25. Represent QA policies, which establish essential QC procedures, that are applicable to environmental laboratories regardless of size and complexity.

Appropriate For The Use of the Data:

Helps ensure that associated environmental data is of known quality and that the quality is adequate for the intended use of the data.

Comment ID #: , Source of Comments (Name): QS Lead on Response (Name):			
Standard Rev. # SECTION# and QS Standard Narrative (To Filled In by Commentor)	**COMMENTwith Rationale to QS (To Be Filled in by Commentor)** **New Wording for Standard (To Be Filled In by Commentor)**	**QS Leader Provided Proposed Change (Commentor Leave Blank)**	**RATIONAL (from QS Leader) (Commentor Leave Blank)**

Attachment E

QS COMMITTEE RESPONSES TO COMMENTS
Quality Systems Committee
April 6, 1999

Standard Rev. #, Section # and QS Standard Narrative	Comments and Proposed Text	QS Response	Rational
	Source of Comments: Jack Hall Quanterra		
5.11.3 item c) In the paragraph the word "preparation" was used twice.	Word should be "preservation"	No change	Direct verbiage from ISO 25, preparation includes preservation
5.13 item a) 17 clear identification .....with values below the "quantitation limit." Delete rest of sentence	Change to .....with values below 3.18 times the MDL....	No change proposed	This section was changed in Rev. 10.
Appendix C – Initial Demonstration of Capability. It must be clarified that the requirement is that the lab must have such a demonstration for each method. Some have interpreted this to mean every analyst, instrument, etc. which would create more economic hardship on the small labs.	Insert at end of first sentence after (5.10.2.1). "An initial demonstration of capability is required for each method or lab SOP used for the method, not each analyst or instrument used for the method."	No change.	Definition from appendix B - *Initial Demonstration of Capability: procedure to establish the ability of the laboratory to generate data of acceptable accuracy and precision*. QS Response: The instruments and analysts used to generate the data are an integral part of generating the data. ***5.10.2.1 Initial Demonstration of Capability*** *d) Initial demonstration of method performance must be completed each time there is a significant change in instrument type, personnel, or test method.* QS Response: A "significant change" is not defined, but the intent seems to be every instrument, every change, and every operator. A requirement for a IDC for each analyst is also addressed in 5.6.2. The small lab argument has been addressed multiple times and our position is based solely on quality.

Standard Rev. #, Section # and QS Standard Narrative	Comments and Proposed Text	QS Response	Rational
Initial Demonstration of Capability Certification Statement. Again implies for each analyst which is not how defined by NELAC (see glossary)	On the form change # 1 "The cited test method/SOP which is in use at this facility for the analysis capability."	# 1 No change.	# 1 QS Response: Same as above.
	Also on the form # 5 uses the word all raw data which is subject to much interpretation best to drop the words "All raw" and start the sentence with Data (…..	#5. No change	#5 QS Response: "Raw Data is defined in appendix B and understood, however, in this phrase, the term raw tends to limit the phrase and could be dropped.
D1.1 item a 1) i & ii Setting requirement for the blank to be less then 1/10 of measured concentration or regulatory limit places value sometimes below the MDL.	Use in the i " ½ of the quantitation limit" and in ii use" ½ of the regulatory limit."	i) No change.	i) QS Response: This seems to be written for samples being tested not to exceed an upper limit.
	Laboratory quantitation limits and regulatory limits may be as low as 2-3X the MDL. This makes control of the method blanks to 10X lower than these levels very difficult to impossible, since it would require measurement well below the MDL. In the case of common laboratory contaminants (methylene chloride, acetone, iron, zinc) there is likely to be a measurable amount of analyte in the method blank. For these analytes, control to ½ the quantitation limit provides reasonable assurance that levels over the quantitation limit in the samples are not due to laboratory contamination.	ii) No change	ii) QS Response: Although the relationship between the regulatory limit and the detection limit may, in some cases, make a detection 1/10 of the regulatory limit impractical, the intent seems to be classifying any detection as contamination.
		QS Response NOTE 1: i) the blank contamination exceeds a concentration greater than 1/10 of the measured concentration of any sample in the associated sample batch ~~and~~or ii) the blank contamination exceeds the concentration present in the samples and is greater than 1/10 of the specified regulatory limit.	QS Response NOTE 1: The "and" that separates i) and ii) makes the sentence mean that both are required to be met. That then makes i) meaningless as written. I would suggest "and" be changed to "or".
		QS Response NOTE 2: ~~Each sample in the affected batch must be assessed against the above criteria to determine if the sample datum is acceptable.~~ Any sample associated with the contaminated blank shall be reprocessed for analysis or the results reported with appropriate data qualifying codes.	QS Response NOTE 2: Also, the first sentence in the second paragraph of D.1.1.a) 1), describes acceptance criteria for an individual sample even though blank contamination is a batch acceptance criteria. I would suggest the sentence be eliminated.

Standard Rev. #, Section # and QS Standard Narrative	Comments and Proposed Text	QS Response	Rational
D1.1.b.1 The NOTE: The Matrix spike (see 2 below) may be used as a control as long as the acceptance criteria are as stringent as the LCS.	DELETE this NOTE. One should not control using a parameter that is effected by the matrix. Not appropriate statement for NELAC.	No change	The key here is that the acceptance criteria of the matrix spikes must be as stringent as the LCS. This would be even more difficult for a lab to accopmplish. Obviously a laboratory would have more success obtaining better recoveries on a "clean" matrix. **But** the note gives the lab some extra flexibility to substitute a matrix spike for an LCS. This in no shape, form or fashion dilutes the standards, but instead gives laboratories with one sample matrix and possibly one client to use the required matrix spikes as batch acceptance, therefore making a LCS not necessary. Again, this will be an option for labs who find utility in it. The majority of labs will use the LCS for obvious reasons; recoveries can be expected to be greater in a laboratory pure water or other "clean" matrices.
Revision 10, Section 5.9.3 insert of Glass syringes at the end.	This maybe interpreted that each syringe would have to be tied to a Certificate. Change "a certificate" to "...vendor documentation for their syringes" attesting to...	No change	This is now in 5.9.4.1e. This is the intent of the standard.
Revision 10, Section 5.9.4.2.1 item F. Results of samples not bracketed by initial calibration standard must be reported as having less certainty...	DELETE this item. This is not appropriate, you do not always run initial calibration standards each time you analyze a parameter let alone at the beginning and the end. Confused with continuing calibration check standards.	One small change for clarification. Add "instrument" between "initial" and "calibration."	This will be consistent with the Note preceding the criteria and d and e. This section is very clear about the definition of initial calibration standards that will be used for quantification.
Revision 10, Section 5.9.4.2.1 Item h	Insert as shown..., if these limits/level are known and achievable by the laboratory.	No change	Standard says,"...if these limits/levels are known by the laboratory, unless these concentration are below the laboratory's demonstrated detection limits."

Standard Rev. #, Section # and QS Standard Narrative	Comments and Proposed Text	QS Response	Rational
5.9.4.2.1 f) "Results of samples not bracketed by initial calibration standards must be reported as having less certainty,…"	This sounds as if calibration curves are required before and after sample analysis, rather than suggesting that target analyte results reported outside of	No change	Current version states "Results of samples not bracketed by an initial instrument calibration standards (within calibration range) must be reported as having less certainty, e.g., defined qualifiers or flags or explained in the case